REMARKS/ARGUMENTS

With entry of the current amendments, claims 1, 2, 5, 6, 7, and 9 have been amended. Claims 11-23 and 3, 5, 6, 8, and 9 were withdrawn by the Examiner as drawn to a non-elected invention. Accordingly, claims 1, 2, 7, and 10 have been examined.

The amendments to the claims add no new matter and are fully supported by the application as filed.

Election requirement

The Examiner withdrew claims 3-5, 8, 9, and 11-23 from examination as allegedly lacking the elected invention. Applicants respectfully submit that claims 5 and 9 were incorrectly withdrawn from examination. Inspection of the sequences shows that Applicants elected invention, the antigenic peptides/vaccines of claims 1-10 and the sequences X-KSSGKLISL-X, wherein X is independently an amino acid or sequence of amino acids with the proviso that X is not identical to the amino acid or amino acids naturally flanking the subsequences in HIV-1, includes the subsequence GEFC**KSSGKLISL**CGDPAK (emphasis added), which is set forth in dependent claims 5 and 9. Thus, this subsequence is a species of X-KSSGKLISL-X. Accordingly, claims 5 and 9 are properly included in the elected invention and Applicants respectfully submit that these claims be rejoined for examination.

Objection to the claims

The objection to claims 1 and 6 is obviated by the amendments to the claims.

For convenience, the rejections are addressed in the order set forth in the Office Action mailed January 22, 2003.

The invention

The invention relates to the identification of peptide sequences associated with long term survival of persons infected with HIV-1. The peptides, also referred to as epitope mimics, were identified by screening peptides display libraries using sera from long term non-

progressor HIV-1 infected individuals. The antibodies that bind to the peptides are HIV-1 specific. Applicants note that the claims currently under examination relate to the sequence X-KSSGKLIS-X. This peptide corresponds to the epitope displayed on phage 195. See, *e.g.*, Figure 2, part a.

Rejection under 35 U.S.C. § 112, second paragraph

Claims 7 was rejected as allegedly lacking proper antecedent basis. The rejection is obviated by Applicants' amendment.

Claim 10 was rejected as allegedly indefinite in the recitation of "does not give rise to HIV-1 specific antibodies to more than twelve other antigenic determinants on HIV-1". The rejection alleges that the recited element does not appear to further limit the invention because this is a quality of the antigenic peptide. Applicants respectfully traverse. Independent claim 1 recites a peptide of 100 amino acids or less in length that comprises the claimed subsequence. The element in question is a functional element in which the antigenic peptide comprising the claimed subsequence also has this characteristic feature. For example, the claimed sequence may be included in a longer peptide with multiple HIV-1 epitopes. Thus, this element further describes such populations of longer peptides. Accordingly, the element appropriately modifies the invention relative to claim 1. Applicants therefore respectfully request withdrawal of the rejection.

Rejection under 35 U.S.C. § 101

Claims 1, 2, 7, and 10 were rejected as allegedly lacking utility. The rejection alleges that the disclosed invention is inoperative and therefore lacks utility. The Examiner describes the invention as being drawn to a vaccine composition for protecting against HIV-1. He then argues that the specification does not teach or described the use of the invention as a vaccine and that no clinical, *in vivo,* or *in vitro* data are provided such that one of skill would be convinced that the proposed utility is sufficiently established. Applicants respectfully traverse.

The Revised Interim Utility Guidelines Training Materials state that an invention must have a specific, substantial, and credible utility; or that the utility requirement may be satisfied by a "well established utility", *i.e.,* a specific, substantial, and credible utility that is well known, immediately apparent, or implied by the specifications' disclosure of the properties of a material alone or taken with the knowledge of one skill in the art. The claimed compositions meet these requirements. Not only are the peptides useful for inducing an immune response *in vivo*, as demonstrated in the specification, but they also have additional, diagnostic utilities *in vitro*.

The claimed peptides and vaccines can be used to diagnose HIV infection

The peptides and vaccines of the inventions have utilities associated with the diagnosis of HIV-1 infection as well as therapeutic utilities. For example, on page 27, the specification teaches that the peptides or antibodies to the peptides can be used as diagnostic reagents and provides exemplary assays for performing such an analysis. In this section, the specification explains that the peptides can be incorporated into an immunological assay to determine whether an HIV-1-infected individual has antibodies to the peptide. As further explained below, the peptides may also be used *in vivo* to raise antibodies to particular epitopes (*see, e.g.,* page 29, lines 7-11). In an alternative diagnostic embodiment, may be used to specifically stimulate HIV-specific B-cells in biological sample from HIV-infected individuals (*see, e.g.,* page 29, lines 12-14). Thus, the specification discloses multiple diagnostic uses for the claimed peptides.

To further support these asserted utilities, exemplary data are provided that show that the peptides can be used to purify antibodies from the sera of HIV-infected patients. When the specific antibodies were tested in immunoblotting, they detected specific HIV proteins (*e.g.,* on page 33, lines 22-24). For example, antibodies to the epitope on phage 195, which corresponds to the peptide under examination (*see, e.g.,* Figure 2), detected gp160 and gp120. As appreciated by one in the art, such antibodies can be used to detect HIV proteins in biological samples.

The claimed epitopes are immunogenic in vivo

Furthermore, the application teaches that the epitopes are immunogenic *in vivo*. In particular, the examples describe immunization of mice and *Rhesus macaque* monkeys with the epitopes identified from the screen of the library. The results showed that the epitopes induced neutralizing antibodies in mice and elicited a specific antibody response in a primate model.

A vaccine composition of the invention is defined as one that elicits an immune response that is antiviral (see, *e.g.*, page 21, lines 7-11). The claimed vaccines are not required to completely protect an individual from HIV-1 infection. As noted above, antibodies resulting from immunization with the peptides have diagnostic utilities. Hence, vaccine compositions comprising peptides to provide such antibodies logically also have utility for raising such antibodies.

Clinical data are not required to meet the utility requirement

Lastly, the MPEP clearly states that the fact that there is no known cure for a disease cannot serve as the basis for a conclusion that an invention lacks utility (see, *e.g.*, MPEP § 2107.03 (VI)). Further, Applicants do not have to prove that a correlation exists between a particular activity, in this case, immunogenicity, and an asserted therapeutic use of a compound as a matter of statistical certainty; nor do Applicants have to provide actual evidence of success in treating human (*see, e.g.*, MPEP2107.03(I)). All that is required is that a reasonable correlation between the activity and the asserted use exist. Applicants have shown that the claimed peptides are immunogenic *in vivo* using both mouse models and a nonhuman primate model. This biological activity reasonably correlates with the asserted utility of using the peptides to induce antibodies. Applicants therefore submit that the use of the peptides as a vaccine is a credible utility.

For the reasons outlined above, the claimed immunogenic peptides and vaccines have specific, credible, and substantial applications. Accordingly, the claims satisfy the utility requirement. Applicants therefore respectfully request withdrawal of the rejection.

Rejection under 35 U.S.C. § 112, first paragraph--written description

Claim 10 was rejected as allegedly not adequately described in the specification. Applicants respectfully traverse. Claim 10 recites both a structural characteristic (the particular sequence recited in claim 1) as well as a functional characteristic (the peptide that comprises the claimed sequence does not give rise to HIV-1-specific antibodies to more than twelve other antigenic determinants on HIV-1). Accordingly, the claim meets the written description requirement. Applicants therefore respectfully request withdrawal of the rejection.

Rejection under 35 U.S.C. § 112, first paragraph--enablement

Claims 1, 2, and 7 were rejected as allegedly not enabled. The Examiner acknowledges that the specification is enabling for an antigenic composition, but contends that it does not provide reasonable enablement for a vaccine that protects against HIV-1. Applicants respectfully traverse. The various teachings in the specification of how to make and use the claimed compositions enable the claims.

As noted above, a vaccine composition of the invention is defined as one that elicits an immune response that is antiviral (see, *e.g.*, page 21, lines 7-11). The claimed vaccines are not required to completely protect an individual from HIV-1 infection. Thus, Applicants demonstration that the peptides elicit antibody responses *in vivo* is sufficient to enable the vaccine claims.

Furthermore, Applicants have taught how to use the peptides diagnostically. The specification provides ample guidance for one of skill to use the peptides as diagnostic reagents directly, or as immunogens to obtain particular antibodies for diagnostic uses (see, arguments in response to the utility rejection). Accordingly, these teachings also enable the claimed compositions. Applicants therefore respectfully request withdrawal of the rejection.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,

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